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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/512,025      | 10/04/2005  | Vishwanath R. Lingappa | UCSF.004.01US       | 6909             |

22798 7590 07/24/2007  
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| EXAMINER |
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DAVIS, MINH TAM B

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| ART UNIT | PAPER NUMBER |
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1642

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| MAIL DATE | DELIVERY MODE |
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07/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/512,025

Applicant(s)

LINGAPPA, VISHWANATH R.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, drawn to a method for detecting a disease-related conformer of prostatic acid phosphatase, using antibodies specific for the conformer of prostatic acid phosphatase.

Group 2, claim(s) 2, drawn to a method for identifying an inhibitor of a disease-related conformer of prostatic acid phosphatase.

Group 3, claims 3, 18-21, drawn to a method for identifying or making an antibody specific for a conformer of prostatic acid phosphatase.

Group 4, claim 4-6, drawn to a method for establishing a prostatic acid phosphatase conformer profile in a population.

Group 5, claim 7, drawn to a method for selecting a treatment, using the prostatic acid phosphatase conformer profile.

Group 6, claims 8-11, drawn to a monoclonal antibody to a conformer of prostatic acid phosphatase.

Group 7, claims 12-14, drawn to a method for detecting prostate cancer.

Group 8, claims 15, 22, drawn to a conformer of prostatic acid phosphatase.

Group 9, claims 16-17, drawn to a method for making a conformer of prostatic acid phosphatase.

Group 10, claims 23-24, drawn to a method for treating a prostate disease, using a disease-related conformer of prostatic acid phosphatase.

The inventions are distinct, each from the other because of the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as groups 1-9 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of group 1 encompasses a method for identifying a disease related conformer of prostatic acid phosphatase, using antibodies specific for a conformer of prostatic phosphatase. Lee et al, 1984, Biochem J, 223: 871-877, teach making fragments of prostatic acid phosphatase, that retain intact disulphide bonds, which prevent unfolding of the polypeptide (p.876, first column, last paragraph). Lee et al teach that thus the fragments contain the entire antigenic active sites of the native, non-denatured prostatic acid phosphatase (p.876, first column, last paragraph, bridging second column, second column, second paragraph). Lee et al teach polyclonal antibodies specific for the native prostatic acid phosphatase (figure 2 and table 2 on page 875). Lee et al teach that in a competitive binding assay, a large excess of these fragments are required to inhibit the binding of these antibodies to the native prostatic acid phosphatase, and that such requirement of an increase in concentration of the fragments is necessary to achieve the characteristic folding of the antigenic sites of the

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native prostatic acid phosphatase (p.876, second column, third paragraph, figure 2 and table 2 on page 875). From the teaching of Lee et al, it is clear that the antibodies to native prostatic acid phosphatase are specific for the conformation or shape of the native prostatic acid phosphatase, because an increase in concentration of the fragments is necessary to achieve the characteristic folding of the antigenic sites of the native prostatic acid phosphatase to displace the binding of the antibodies to the native prostatic acid phosphatase. Thus, the shared technical feature of the claimed invention lacks novelty and does not make a contribution over the prior art.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS  
July 18, 2007

/Larry R. Helms/

Supervisory Patent Examiner